

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known ☐ ☐ ☐

| | |
|------------------------|---------------------------|
| Application Number | 10,510,370 |
| Filing Date | May 9, 2005 |
| First Named Inventor | Donald Johnstone Naismith |
| Art Unit | To Be Determined |
| Examiner Name | To Be Determined |
| Attorney Docket Number | BTG0005-100 (143593US01) |

(Use as many sheets as necessary)

| | | | |
|-------|---|----|---|
| Sheet | 1 | of | 4 |
|-------|---|----|---|

[illegible]

| FOREIGN PATENT DOCUMENTS | | | | | | |
|---------------------------------|-----------------------|--|---|---|---|----------------|
| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | Publication Date/Filing Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ^e |
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (<i>if known</i>) | | | | |
| /B.P. | AB | WO 90/04403 | 05-03-1990 | Univ. of Calif. | | |
| | AC | WO 95/35038 | 12-28-1995 | Singer | | |
| | AD | JP 06 345660 | 12-20-1994 | Earth Seiyaku KK | | |
| | AE | JP 06 345664 | 12-20-2004 | Tomita | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

| | | | |
|--|-------------|--|--|
| Substitute for form 1449B/PTO | | Application Number <u>10/510,370</u> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Filing Date <u>May 9, 2005</u> | |
| | | First Named Inventor <u>Donald Johnstone Naismith</u> | |
| | | Art Unit <u>To Be Determined</u> | |
| | | Examiner Name <u>To Be Determined</u> | |
| | | Attorney Docket Number <u>BTG0005-100 (143593US01)</u> | |
| (Use as many sheets as necessary) | | | |
| Sheet <u>2</u> | of <u>4</u> | | |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| /B.P./ | AF | Appel et al., "A clinical trial of the effects of dietary patterns on blood pressure," <i>N. Engl. J. Med.</i> , (1997) 336:1117-1124. | |
| /B.P./ | AG | Bates et al., "Micronutrients: highlights and research challenges from the 1994-5 National Diet and Nutrition Survey of people aged 65 years and over," <i>Br. J. Nutr.</i> (1999) 82:7-15. | |
| /B.P./ | AH | Boegehold et al., "Importance of Dietary Chloride for Salt Sensitivity of Blood Pressure," <i>Hypertension</i> (1991) 17(1 Suppl):158-161. | |
| /B.P./ | AI | Cappuccio et al., "Does potassium supplementation lower blood pressure? A meta-analysis of published trials," <i>J. Hypertens.</i> (1991) 9:465-473. | |
| /B.P./ | AJ | Dyer et al., "Body mass index and associations of sodium and potassium with blood pressure in INTERSALT," <i>Hypertension</i> (1994) 23:729-736. | |
| /B.P./ | AK | Freedman et al., "Salt and blood pressure. Conventional wisdom reconsidered," <i>Eval. Rev.</i> (2001) 25:267-287. | |
| /B.P./ | AL | Frisancho et al., "Blood pressure in blacks and whites and its relationship to dietary sodium and potassium intake," <i>J. Chronic. Dis.</i> (1984) 37:515-519. | |
| /B.P./ | AM | Geleijnse et al., "Sodium and potassium intake and blood pressure change in childhood," <i>Brit. Med. J.</i> (1990) 300:899-902. | |
| /B.P./ | AN | Giaconi et al., "Seasonal influences on blood pressure in high normal to mild hypertensive range," <i>Hypertension</i> (1989) 14:22-27. | |
| /B.P./ | AO | Graudal et al., "Effects of sodium restriction on blood pressure, renin, aldosterone, catecholamines, cholesterol, and triglyceride: a meta-analysis," <i>J. Amer. Med. Assoc.</i> (1998) 279:1383-1391. | |
| /B.P./ | AP | Gregory et al., <i>The Dietary and Nutritional Survey of British Adults</i> , HMSO London (1990) 154-158. | |

| | | | |
|--------------------|-----------------------|-----------------|------------|
| Examiner Signature | /Benjamin J. Packard/ | Date Considered | 08/22/2007 |
|--------------------|-----------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

1020 Rec'd PCT/PTO 10 AUG 2005

PTO/SB/08b(08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if ☒ _____

| | |
|------------------------|---------------------------|
| Application Number | 10/310,370 |
| Filing Date | May 9, 2005 |
| First Named Inventor | Donald Johnstone Naismith |
| Art Unit | To Be Determined |
| Examiner Name | To Be Determined |
| Attorney Docket Number | BTG0005-100 (143593US01) |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|---------------------|-----------------------|---|----------------|
| /B.P./ | AQ | Jansen et al., "The effect of a change in ambient temperature on blood pressure in normotensives," <i>J. Hum. Hypertens.</i> (2001) 15:113-117. | |
| /B.P./ | AR | Kannel., "Blood pressure as a cardiovascular risk factor: prevention and treatment," <i>J. Amer. Med. Assoc.</i> (1996) 275:1571-1576. | |
| /B.P./ | AS | Kawano et al., "Effects of potassium supplementation on office, home and 24-H blood pressure in patients with essential hypertension," <i>Am. J. Hypertens.</i> (1998) 10(11):1141-1146. | |
| | AT | Koneth et al., "Potassium and Arterial Hypertension - are Potassium Supplements Useful?" <i>Schweizerische Rundschau Fuer Medizin Praxis</i> (2000) 38(89):1499-1505. (German). | |
| /B.P./ | AU | Kotchen et al., "Dietary sodium and blood pressure: interactions with other nutrients," <i>Am. J. Clin. Nutr.</i> (1997) 65(2Suppl):708S-711S. | |
| /B.P./ | AV | Langford, "Dietary potassium and hypertension: epidemiologic data," <i>Ann. Intern. Med.</i> (1983) 98:770-772. | |
| /B.P./ | AW | Materson et al., "Single-drug therapy for hypertension in men. A comparison of six antihypertensive agents with placebo," <i>N. Engl. J. Med.</i> (1993) 328:914-921. | |
| /B.P./ | AX | Matlou et al., "Potassium supplementation in blacks with mild to moderate essential hypertension," <i>J. Hypertens.</i> (1986) 4:61-64. | |
| /B.P./ | AY | Morris et al., "Normotensive salt sensitivity: effects of race and dietary potassium," <i>Hypertension</i> (1999) 33:18-23. | |
| /B.P./ | AZ | Sacks et al., "Low blood pressure in vegetarians: effects of specific foods and nutrients," <i>Am. J. Clin. Nutr.</i> (1988) 48(3 Suppl):795-800. | |
| /B.P./ | BA | Sacks et al., "Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet," <i>N. Engl. J. Med.</i> (2001) 344:3-10. | |

Examiner
Signature

/Benjamin J. Packard/

Date
Considered

08/22/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

| | | | |
|---|---|--------------------------|---------------------------|
| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | Application Number | 10/510,370 |
| | | Filing Date | May 9, 2005 |
| | | First Named Inventor | Donald Johnstone Naismith |
| | | Art Unit | To Be Determined |
| | | Examiner Name | To Be Determined |
| | | Attorney Docket Number | BTG0005-100 (143593US01) |
| Sheet | 4 | of | 4 |

| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| /B.P./ | BB | Shore et al., "A randomized crossover study to compare the blood pressure response to sodium loading with and without chloride in patients with essential hypertension," <i>J. Hypertens.</i> (1988) 6:613-617. | |
| /B.P./ | BC | Siani et al., "Controlled trial of long term oral potassium supplements in patients with mild hypertension," <i>Br. Med. J. (Clin. Res. Ed.)</i> (1987) 294:1453-1456. Double check author's name | |
| /B.P./ | BD | Sinaiko et al., "Effect of low sodium diet or potassium supplementation on adolescent blood pressure," <i>Hypertension</i> (1993) 21:989-994. | |
| /B.P./ | BE | Smith et al., "Socio-economic differentials in health: the role of nutrition," <i>Proc. Nutr. Soc.</i> (1997) 56:75-90. | |
| /B.P./ | BF | Rouse et al., "Blood-pressure-lowering effect of a vegetarian diet: controlled trial in normotensive subjects," <i>Lancet</i> (1983) 1:5-10. | |
| /B.P./ | BG | Ward et al., "Tokelau Island Migrant Study," <i>Hypertension</i> (1980) 2(Suppl. 1):43-54. | |
| /B.P./ | BH | Watanabe et al., "Potassium and Hypertension," <i>Nutrition Reviews</i> (1998) 5 (Part 1, No. 56):151-153. | |
| /B.P./ | BI | Whelton, "Epidemiology of hypertension," <i>Lancet</i> (1994) 344:101-106. | |
| /B.P./ | BJ | Whelton et al., "Effects of oral potassium on blood pressure. Meta-analysis of randomized controlled clinical trials," <i>J. Amer. Med. Assoc.</i> (1997) 277:1624-1632. | |
| /B.P./ | BK | Wilson et al., "Effects of potassium on blood pressure in salt-sensitive and salt-resistant black adolescents," <i>Hypertension</i> (1999) 34:181-186. | |
| /B.P./ | BL | International Search Report dated August 6, 2003 for International Application No. PCT/GB03/01512. | |

| | | | |
|--------------------|-----------------------|-----------------|------------|
| Examiner Signature | /Benjamin J. Packard/ | Date Considered | 08/22/2007 |
|--------------------|-----------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.